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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,513	12/21/2001	Juan Mantelle	041457-0630	4098

22428 7590 09/19/2005

FOLEY AND LARDNER
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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,513	MANTELLE ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/15/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,16-23,25-32 and 34-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,16-23,25-32 and 34-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-14, 16-23,25-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Example 1 and disclosed components in example 1, does not reasonably provide enablement for other components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a composition and method of treatment using a flexible,finite system which delivers methylphenidate in an amount and rate sufficient to increase the methylphenidate plasma concentration of a subject being treated over a period of about 6-16 hours, followed by a steady decrease in the plasma concentration of metylphenidate.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses certain embodiments which appear to fall within the scope of the claimed invention. See rejections below. However, the prior art discloses closely related embodiments which nonetheless exhibit characteristics outside the scope of the claimed invention. See WO 99/30694, Examples 4,5. As such, predictability in the art appears to be low.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification discloses various adhesives and amounts which may be used, however, the only formulations tested are a mixture methylphenidate with silicone adhesive and acrylic adhesive.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they can contain any ingredient in addition to the methylphenidate and adhesive, or a mixture of about 10 to 30 wt% methylphenidate with about 30-50%wt each of any acrylic adhesive and any silicone adhesive, with the proviso that the product delivers methylphenidate in an amount and rate sufficient to increase the plasma concentration of methylphenidate over a period of about 6-16 hours, followed by a steady decrease in the plasma concentration of methylphenidate. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what other ingredients can be added with out adversely effecting the time curve of the plasma concentration. Further, the prior art discloses compositions containing methylphenidate, silicone adhesive and acrylic adhesive in amounts falling within the disclosed and claimed amounts, which exhibit a plasma concentration curve which is not within about 6-16 hours. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what mixtures of methylphenidate and adhesive will result in the claimed plasma concentration time curve.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5,7-14, 16-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/30694.

WO 99/30694 expressly discloses a composition containing 30 wt% methylphenidate, 40wt% Duro-Tak 87-2296 and 30 wt% Bio-PSA X7-4403 and 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 56 wt% Bio-PSA X7-4403 having the flux profiles shown in Figure 1, and a composition containing 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 60 wt% Bio-PSA X7-4403 having the flux profile of Figure 3 falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-5,7-14, 16-23, 25-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/30694.

WO 99/30694 discloses a composition containing 30 wt% methylphenidate, 40wt% Duro-Tak 87-2296 and 30 wt% Bio-PSA X7-4403 and 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 56 wt% Bio-PSA X7-4403 having the flux profiles shown in Figure 1, and a composition containing 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 60 wt% Bio-PSA X7-4403 having the flux profile of Figure 3. It is disclosed that methylphenidate is effective in treating attention deficit disorder and attention deficity/hyperactivity disorder (Pg. 1).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose use of the prior art compositions in the treatment of ADD and ADHD. However, the prior art amply suggests the same as it disclosed that methylphenidate is effective in treating said conditions and discloses compositions falling within the scope of the claimed compositions which contain methylphenidate. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the prior art compositions with the expectation that said compositions would be effective in treating said conditions.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-5, 7-9, 39 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 01/10420.

WO 01/10420 expressly discloses a patch which contains methylphenidate which delivers at a rate falling within the scope of the claims wherein there is no degradation of methylphenidate (Pg. 5, 1st paragraph, Pgs. 18, 19, Examples 4, 5, Figures 3, 4).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

As preliminary matter, the declaration is not commensurate in scope with the claimed subject matter as the only example given is the example set forth in the Specification which is in sufficient to enable the full scope of the claimed invention. As such, the Declaration must show possession of the invention as is disclosed in the cited reference. Applicant has not shown that the declaration shows completion of the invention commensurate with the extent of the invention as shown in the cited reference. The only discussion which relates to this issue is with respect to 2 ng/ml, however, this does not make the declaration commensurate in scope with the invention as shown in the cited reference. WO 01/10420 arrives at the 2ng/ml by a completely different transdermal patch from that set forth in the declaration. The declaration discloses 20 wt% of methylphenidate, 40wt% of BIO-PSA 7-4102 and 40 wt% Gelva 3087. WO 01/10420 discloses a patch containing 10% methylphenidate and 5, 10 or 20% IPM and cross-linked block polymer which is prepared from of (meth)acrylate, acrylamide monomers and cross-linking agents and does not contain a silicon pressure sensitive adhesive.

Claims 1-5,7-14,16-23, 25-32, 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/10420 in view of Miranda et al. (US Pat. 5,656,286).

WO 01/10420 discloses a patch which contains methylphenidate which delivers the majority of the methylphendiate over the desired period, such as 12 hours, after which plasma

concentrations drop at a rate falling within the scope of the claims wherein there is no degradation of methylphenidate (Pg. 5, 1st paragraph, Pg. 14, Pgs. 18, 19, Examples 4, 5, Figures 3, 4). It is taught that limiting active functionalities, including acidity, of the adhesive monomers is desired to avoid unnecessary degeneration of the methylphenidate and that preferred level of residual monomers is below 2000 ppm (Pgs. 8-10). It is taught that the drug delivery profile is advantageous because the patches are exhausted after use and are not suitable for abuse (Pg. 14). It is taught that the patches are suitable for treatment of ADD and ADHD (Pg. 15).

Miranda et al. teaches that by combining and adjusting the relative proportions acrylic and silicone pressure sensitive adhesives the transdermal permeation rate of drugs, such as methylphenidate, can be adjusted and the adhesive composition advantageously permits selectable loading of the drug (Columns 8, 9, Column 28, line 7).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of treating ADD or ADHD with a methylphenidate patch or the combined use of acrylic and silicone based adhesives. However, the prior art amply suggests the same as it is known that methylphenidate is effective in treating ADD and ADHD and it is known to prepare patches containing methylphenidate. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the patches would be effective in treating ADD or ADHD, would provide a drug delivery profile as that claimed in the present invention and prevent degradation of the methylphenidate.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-5,7-14, 16-23, 25-42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/30694.

WO 99/30694 expressly discloses a composition containing 30 wt% methylphenidate, 40wt% Duro-Tak 87-2296 and 30 wt% Bio-PSA X7-4403 and 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 56 wt% Bio-PSA X7-4403 having the flux profiles shown in Figure 1, and a composition containing 20 wt% methylphenidate, 20wt% Duro-Tak 87-2296 and 60 wt% Bio-PSA X7-4403 having the flux profile of Figure 3 falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner notes that with respect to the rejections above, the rejections are based on the finding that the claims are only entitled to the priority date of 12/21/2001. There is no explicit disclosure in the priority documents for the limitation "6-16 hours", "at least about 8 hours", "about 6-12 hours", "0.06 (ng/ml)/hour to 6 (ng/ml)/hour", and "0.4 (ng/ml)/hour to 2.5 (ng/ml)/hour."

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
September 13, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600